UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT SHIPMAN

Appeal No. 2006-0209
Application No. 09/786,105

ON BRIEF

Before ELLIS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves a claim to a kit for determining antibiotic resistance in Mycobacterium tuberculosis, which the examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 134. We affirm.

Background

"M. tuberculosis can be resistant to all antibiotics that are currently used to treat tuberculosis patients. Antibiotic resistance is due to acquired point mutations in target genes in the genome of M. tuberculosis." Specification, page 1. Resistance to the antibiotic rifampicin is caused by mutations in the rpoB gene. See page 2. The specification discloses "[a]mplication and cycle sequencing primer sets . . . for the

detection and analysis of antibiotic resistance-associated mutations in defined regions of the rpoB" gene and other genes associated with M. tuberculosis antibiotic resistance. Page 3.

Two specific primers are disclosed for amplifying and sequencing the region of the rpoB gene associated with mutations that cause resistance to rifampicin. See pages 4-5. (Although the specification separately lists the primers used for amplification (SEQ ID NOs 1 and 2) and those used for sequencing (SEQ ID NOs 3 and 4), the two sets of primers are identical: SEQ ID NO:1 is the same as SEQ ID NO:3, and SEQ ID NO:2 is the same as SEQ ID NO:4.)

Discussion

1. Claim construction

Claim 14 is the only claim pending and reads as follows:

14. A kit for evaluation of antibiotic-resistance mutations in a sample of Mycobacterium tuberculosis, comprising pairs of amplification primers and matched pairs of sequencing primers for amplification and sequencing, respectively, of at least the rpoB, katG, rpsL/s12 and 23S genes of M. tuberculosis, wherein the amplification and sequencing primer pairs in the kit include at least one combination of an amplification primer pair and a matched sequencing primer pair for amplification and sequencing of a common gene selected from among the following combinations of primer pairs:

(a) amplification primers of Seq. ID Nos. 1 and 2 in combination and sequencing primers of SEQ ID Nos. 3 and 4;

(b) amplification primers of Seq. ID Nos. 6 and 7 in combination and sequencing primers of Seq ID Nos. 8 and 9;

(c) amplification primers of Seq. ID Nos. 11 and 12 in combination and sequencing primers of Seq. ID Nos. 13 and 14;

(d) amplification primers of Seq. ID Nos. 16 and 17 in combination and sequencing primers of Seq ID Nos. 18 and 19;

(e) amplification primers of Seq. ID Nos. 21 and 22 in combination and sequencing primers of Seq ID Nos. 23 and 24;

(f) amplification primers of Seq. ID Nos. 26 and 27 in combination and sequencing primers of Seq. ID Nos. 28 and 29;

(g) amplification primers of Seq. ID Nos. 31 and 32 in combination and sequencing primers of Seq. ID Nos. 33 and 34;

(h) amplification primers of Seq. ID Nos. 36 and 37 in combination and sequencing primers of Seq. ID Nos. 38 and 39;

(i) amplification primers of Seq. ID Nos. 41 and 42 in combination and sequencing primers of Seq. ID Nos. 43 and 44; and

(j) amplification primers of Seq. ID Nos. 46 and 47 in combination and sequencing primers of Seq. ID Nos. 48 and 49.

Thus, claim 14 is directed to a kit comprising a combination of primers that can be, among other things, the amplification primers of SEQ ID NOs 1 and 2 combined with the sequencing primers of SEQ ID NOs 3 and 4. As noted above, SEQ ID NOs 1 and 2 are identical to SEQ ID NOs 3 and 4, respectively, so the claimed kit need only comprise the pair of primers represented by SEQ ID NOs 1 and 2.

2. Obviousness

The examiner rejected claim 14 under 35 U.S.C. § 103 as obvious in view of De Beenhouwer,[1] Heym,[2] and Foxall.[3] The examiner reasoned that De Beenhouwer teaches "a set of primers in the form of a kit to evaluate antibiotic resistance spectrum of mycobacteria, wherein the instant SEQ ID Nos. 1 and 3 match with complete homology to the primer P2 of the disclosure of De Beenhouwer et al. . . . However,

[1] De Beenhouwer et al., WO 95/33851, published December 14, 1995
[2] Heym et al., U.S. Patent 5,851,763, issued December 22, 1998.
[3] Foxall et al., U.S. Patent 5,985,569, issued November 16, 1999.

De[ ]Beenhouwer et al. did not teach SEQ ID Nos. 2 and 4." Examiner's Answer, page 3. The examiner relied on Heym and Foxall to suggest the primer of SEQ ID NO:2. Id.

Appellants concede that De Beenhouwer "teaches primers for evaluation of antibiotic resistance in mycobacteria, and teaches a sequence that matches Seq. ID Nos. 1 and 3." Appeal Brief, page 3. Appellants argue, however, that Heym and Foxall do not suggest the specific primer represented by SEQ ID NO:2. See id., pages 6-8.

We agree with the examiner that the claimed kit is obvious over the prior art, although we find it unnecessary to rely on the computer program disclosed by Foxall. As everyone acknowledges, De Beenhouwer teaches the primer of SEQ ID NO:1 (primer P2) but does not teach the primer of SEQ ID NO:2.

What has not been made clear in the record, however, is that De Beenhouwer teaches a primer (P6) that is almost identical to SEQ ID NO:2. See De Beenhouwer, page 39. In addition, De Beenhouwer's primer P6 is used in combination with P2 (the primer that is identical to instant SEQ ID NO:1). See page 25.

De Beenhouwer's primer P6 and SEQ ID NO:2 of the instant application have the following sequences:

P6:	TACGGCGTTTCGATGAACC
SEQ ID NO:2:	TACGGCGTTTCGATGAACCC

Thus, SEQ ID NO:2 is identical to De Beenhouwer's primer P6, except that SEQ ID NO:2 has one additional nucleotide on the 3' end.

Heym discloses the sequence of the M. tuberculosis rpoB gene. See column 6, lines 8-9, and SEQ ID NO:59. Based on this sequence, a person of ordinary skill in the art would have known that the P6 primer disclosed by De Beenhouwer could be

extended by one nucleotide in the 3' direction by adding an additional cytosine (C) residue to it. (P6 corresponds to the complement of the rpoB sequence from bases 409 to 428; extending it by one nucleotide in the 3' direction would have involved adding the complement of the base at position 408, which is disclosed to be G - the complement of G is C.)

A person of ordinary skill in the art would have reasonably expected the primer pair disclosed by De Beenhouwer to provide identical PCR amplification properties whether the P2 primer was used in combination with the P6 primer itself or in combination with P6 extended by a single nucleotide, as recited in SEQ ID NO:2 of the instant application. Thus, the P6 primer disclosed by De Beenhouwer would have made obvious the primer of SEQ ID NO:2.

Since the kit defined by instant claim 14 does not differ in any nonobvious way from the kit disclosed by De Beenhouwer, claim 14 is unpatentable under 35 U.S.C. § 103.

Summary

We affirm the rejection of claim 14 under 35 U.S.C. § 103. Since our reasoning differs from that of the examiner, however, we designate our affirmance as a new ground of rejection under 37 CFR § 41.50(b) in order to give Appellant a fair opportunity to respond.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of

rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED

Joan Ellis)
Administrative Patent Judge)
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)
Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
Lora M. Green)
Administrative Patent Judge)

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